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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,637	06/01/2006	Ryuji Ueno	Q76459	8742

23373 7590 06/25/2010

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,637	UENO, RYUJI	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *2 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks filed 03/22/10 and the Information Disclosure Statement (IDS) filed 12/29/05 is acknowledged.

Applicant's election without traverse of species (b) prostaglandin compound in the reply filed on 22 March 2010 is acknowledged. Applicant's election of species (d) formula (III), hydrogen or hydroxy is also acknowledged. Upon further review and consideration, the species election requirement between the formulas I and III (species c & d) has been withdrawn. Thus, only the election of species (between species a & b) has been maintained.

Claims 2 and 3 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/22/10.

Claims 1-19 are pending in this action. Claims 2 and 3 have been withdrawn. Claims 1 and 4-19 have been examined in this action. Claims 1 and 4-19 are rejected.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 29 December 2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Objections

Claim 1 is objected to because of the following informalities: The term "An" should instead be recited as "A" to read as "A composition", rather than "An composition". Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueno et al. (hereinafter "Ueno") (U.S. Pat. No. 6,583,174).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ueno ('174) discloses a composition comprising a bicyclic compound and a glyceride compound and a method for stabilizing the bicyclic compound comprising the step of admixing the same with a glyceride (column 1, line 9 - col. 3, line 36). In one

embodiment, the composition may comprise the bicyclic compound of formula (III), glyceride and an enteric coating in which the bi-cyclic compound is present in a ratio of at least 1:1, especially, 20:1 with respect to its tautomeric monocyclic compound. The composition may be formulated as capsule and outer surface of the capsule may be coated by the enteric coating, or enteric materials may be compounded into the capsule base (col. 21, line 21 – col. 22, line 47).

The compound of formula (III) may be provided as solid product comprising substantially no monocylic tautomer of the same and the present invention also covers a composition comprising the compound of formula (III) and a enteric coating, wherein the composition comprises substantially no monocyclic tautomer of the compound (col. 4, line 60 – col. 5, lines 1-32).

The instant claims are anticipated by Ueno.

* * * * *

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueno et al. (hereinafter "Ueno") (EP 0979651).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ueno ('651) discloses an anti-portal hypertensive agent comprising a 15-keto-prostaglandin compound as an active ingredient (Abstract). The composition is

administered by oral administration (page 6, lines 7-15). Examples of solid compositions include tablets and pills that may be coated with an enteric coating or gastroenteric film (p. 6, lines 26-34). The formulas and compositions of the present invention are encompassed by Ueno, who discloses various prostaglandin compounds of the present invention. The instant claims are anticipated by Ueno.

* * * * *

Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueno et al. (hereinafter "Ueno") (WO 03/030912).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ueno ('912) discloses a prostaglandin compound as a chloride channel opener (Abstract). The composition is administered by oral administration (page 23, lines 10-19). Examples of solid compositions include tablets and pills that may be coated with an enteric coating or gastroenteric film (p. 25, lines 5-21). The formulas and compositions disclosed in instant claims 5-19 are encompassed and disclosed by Ueno, who discloses various prostaglandin compounds of the present invention.

The instant claims are anticipated by Ueno.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (hereinafter "Ueno") (U.S. Pat. No. 6,583,174).

Ueno as stated above, teaches a composition comprising a bicyclic compound and a glyceride compound and a method for stabilizing the bicyclic compound comprising the step of admixing the same with a glyceride (column 1, line 9 - col. 3, line 36). In one embodiment, the composition may comprise the bicyclic compound of formula (III), glyceride and an enteric coating in which the bi-cyclic compound is present in a ratio of at least 1:1, especially, 20:1 with respect to its tautomeric monocyclic compound. The composition may be formulated as capsule and outer surface of the

capsule may be coated by the enteric coating, or enteric materials may be compounded into the capsule base (col. 21, line 21 – col. 22, line 47).

The compound of formula (III) may be provided as solid product comprising substantially no monocylic tautomer of the same and the present invention also covers a composition comprising the compound of formula (III) and a enteric coating, wherein the composition comprises substantially no monocyclic tautomer of the compound (col. 4, line 60 – col. 5, lines 1-32).

The compositions and formulas provided by Ueno read on the limitations of instant claims 5-19. The teachings of Ueno amply demonstrate that it would be *prima facie* obvious to utilize any bicyclic prostaglandin compounds provided in an oral formulation in combination with a glyceride with the expected result of obtaining improved pharmaceutical activity and stability. The reference is clearly suggestive of a composition comprising a bicyclic prostaglandin whereby the active agent can be provided either as a mixture with the enteric coating or alternatively the enteric coating can be supplied as a coating for the outer surface of the dosage form (i.e., capsule).

* * * * *

Claims 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (hereinafter "Ueno") (EP 0979651).

Ueno ('651), as stated above, teaches an anti-portal hypertensive agent comprising a 15-keto-prostaglandin compound as an active ingredient (Abstract). The composition is administered by oral administration (page 6, lines 7-15). Examples of solid compositions include tablets and pills that may be coated with an enteric coating or

gastroenteric film (p. 6, lines 26-34). The formulas and compositions of the present invention are encompassed by Ueno, who discloses various prostaglandin compounds of the present invention. Thus, the compositions and formulas provided by Ueno read on the limitations of instant claims 5-19. The teachings of Ueno amply demonstrate that it would be *prima facie* obvious to utilize any prostaglandin compounds provided in an oral formulation in combination with application of enteric coatings in order to effectively treat portal hypertension.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

June 21, 2010